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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,493	02/05/2002	Lorraine E. Pena	C-3528/2/US	1201

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,493	PENA ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1615	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-22 and 24-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-22 and 24-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Acknowledgment of Papers Received: Amendment and Response dated 4/23/03.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 3-22, and 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barbachyn et al (USPN 5,688,792), Borgulya et al (USPN 5,574,055), Kaplan et al (USPN 4,727,070), and Miyauchi (USPN 4,900,730).

Claims 1, and 3-20 are drawn to a composition comprising a, oxazolidinone in the form of a suppository, where the carrier is lipophilic. The claims recite the oxazolidinone's preferred structure. Subsequent claims limit the concentrations and species of the lipophilic carrier and the oxazolidinone. Claims 21, 22 and 24-29 are drawn to method of treating a gram-positive bacterial infection with the composition of claims 1 and 3-22. Subsequent claims limit the dosage regimen of the treatment.

Barbachyn et al discloses oxazolidinone antimicrobial compounds. The compounds have an identical structure to the compounds of the present invention (Abstract). The compounds of the reference can be formulated into capsules, dispersed granules and similar pharmaceutical

dosage forms (col. 6, lin. 45 – 65). Some of the carriers include lipophilic substances such as waxes, cocoa butter. What is lacking in the reference is an explicit disclosure of a rectal suppository, yet capsules are disclosed. These capsules could be manipulated within the level of skill in the art to be used rectally. It would be within the level of skill in the art to modify a capsule for rectal suppository administration.

Borgulya et al discloses a suppository formulation comprising an oxazolidinone antimicrobial agent (Example A). Though the active agent is a differing oxazolinidone agent, a skilled artisan would be able to substitute the compound of Barbachyn into that of Borgulya and expect the suppository to deliver the same antimicrobial effects as intended by Borgulya since the active agents are in the same class of compounds. The reference discloses that the active agents are

Kaplan et al discloses a suppository formulation comprising oxazolinidone compounds, where the lipophilic carrier is a hard fat (Example 7). Again the active agent differs from that of the claimed invention, but a skilled artisan would be able to substitute the oxazolidinone of Barbachyn into the formulation with an expectation of success since the compounds are in the same class and are used to a similar end.

With regard the to the particle size of the compound, the combination of micronized antibacterial agents, lipophilic carriers in a rectal suppository is well known in the art. Miyauchi discloses a rectal suppository where the active antibacterial agents (which are effective against gram-positive bacterial infections) are micronized from 1 – 50 microns, and dissolved in the hard fat Witepsol H-15 (col. 5 – 24 – 64; Examples). Though the particles of the reference fall within

a wide range, the micronizing of particles is well within the level of one of ordinary skill in the art.

The claims also recite that a further antibacterial agent is additionally included in the dosage form that also is effective against gram-positive bacterial infections. Though not explicitly taught by the cited references, it is obvious to combine like compounds. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. *See* In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). It would have been obvious to combine any of the composition well known in the art to be affective against gram-positive bacterial infections (those taught by Miyauchi for instance), with any of the oxazolidinone compounds of the other cited reference.

With this in mind a skilled artisan would have been motivated to combine the teachings and suggestions of the art. A skilled artisan would be motivated to include the compounds of Barbachyn into any of the compositions of Borgulya. A skilled artisan would have included the hard fat of Kaplan. The skilled artisan would have followed the knowledge of micronizing antibacterial agents and combining them with hard fats into rectal suppositories shown in Miyauchi. It also would have been obvious to the artisan to include other antibacterial agents in order to increase the bacterial infection fighting power of the compound. This combination of teachings, compositions and suggestions would result in a rectal suppository comprising a hard fat (Witepsol W or H series), an oxazolidinone (Barbachyn) compound, and a further antibacterial agent, all of which would be effective in treating or preventing bacterial infections

resulting from gram-positive bacteria. A skilled artisan would be motivated to combine these teachings in order to provide a stable composition with effective pharmacokinetics to treat infection. A skilled artisan also would have been motivated by the antibacterial properties of the oxazolidinone compound to use this compound in a method to treat infections rectally including the compound of Barbachyn. It would have been obvious to combine the teachings, and suggestions as described here, at the time of the invention, with an expected result of a rectal suppository effective in treating bacterial infection.

Response to Amendment

4. The Declaration under 37 CFR 1.132 filed 4/18/03 is insufficient to overcome the rejection of claims 1-29 based upon specific references under 35 USC 102 and 103 as set forth in the last Office action because: The declaration fails to set forth criticality to the specific formulation beyond that which is known in the prior art. The prior art discloses a compound with an identical structure, and suggests its combination into the delivery form of applicant. It is well within the level of skill in the art to modify the delivery of a compound given the pharmaceutically acceptable excipients. The declaration claims unexpected results yet does not differentiate the claimed invention for the combination present in the prior art.

Response to Arguments

5. Applicant's arguments with respect to claims 1-29 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young
July 9, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600